UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,486	01/04/2002	Andrew M. Scharenberg	B0662/7026	4102

23628 7590 03/29/2004

WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,486	SCHARENBERG, ANDREW M.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,16,20,24,25,32,34 and 36* is/are pending in the application.

4a) Of the above claim(s) *2,3,5,16,20,24,25,32 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6-9,12 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III and nucleic acid of SEQ ID NO: 29 as elected species in Paper filed on January 26, 2004 is acknowledged.

Claims 1-9, 12, 16, 20, 24-25, 32, 34 and 36 are pending in the instant application.

Claims 2-3, 5, 16, 20, 24-25, 32 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on January 26, 2004.

Claims 1, 4, 6-9, 12 and 34, in so far as they are directed to an isolated nucleic acid molecule of SEQ ID NO: 29 encoding a polypeptide of SEQ ID NO: 30 are under examination in the instant office action.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 4, 6-9, 12 and 34 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein

and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. It is clear from the instant

specification that the claimed novel nucleic acid encodes a protein that belongs to "a novel family of calcium channel polypeptides" (page 1, lines 3-4 of the instant specification). More specifically, "[t]his newly identified family of calcium channel polypeptides is designated, "SOC" or "CRAC" or "ICRAC" for Store Operated Channels or Calcium Release Activated Channels" (page 2, lines 4-6). It is further asserted that "SOC/CRAC calcium channel polypeptides are transmembrane polypeptides that modulate Ca^{2+} flux "into" and "out of" a cell, for example, in certain instances they may be activated upon depletion of Ca^{2+} from intracellular calcium stores, allowing Ca^{2+} influx into the cell" (page 2, lines 8-10).

In the absence of knowledge of the biological significance of this specific nucleic acid of SEQ ID NO: 29 and encoded protein of SEQ ID NO: 30 corresponding to SOC-3/CRAC-2 (page 9, line12), there is no immediately obvious patentable use for the polynucleotide or the encoded protein. The disclosure of the pattern of expression of SOC-3/CRAC-2 in plurality of the human tissue at different levels (last paragraph at page 10) does not provide for specific physiological function of SOC-3/CRAC-2 polypeptide, which, if disclosed, could lead to a specific substantial and credible utility of the claimed invention. According to the specification of the instant application, the instant claimed SOC-3/CRAC-2 molecules "are believed to be useful for modulating calcium transport into and out of [...]intracellular stores and for the treatment of disorders that are characterized by aberrant calcium transport into and out of such intracellular stores" (page 2, lines 11-13) and, further, that "SOC/CRAC calcium channels play an important role in cellular calcium homeostasis by, e.g., modulating the supply of calcium to refill intracellular stores when depleted". The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant nucleic acid or

encoded protein are associated with any diseases or disorder. To employ the DNA and the protein in the future methods for generation of antibodies or diagnostic assays is not a "real world" utility because it would eventually relate to a protein for which no biological function is known. The instant application also fails to demonstrate use of the DNA or the protein as a marker for any specific disease or condition (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the administration of the novel SOC-3/CRAC-2 calcium channel protein or DNA would prevent or treat a condition or disease, including pathological conditions associated with calcium homeostasis, as implied by the specification. To employ a nucleic acid and the encoded protein SOC-3/CRAC-2 of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a substantial "real world" use for the nucleic acid and the protein encoded thereby in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 4, 6-9, 12 and 34 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a

well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, claim 34 is directed to a pharmaceutical composition comprising a pharmaceutically effective amount of an isolated nucleic acid of SEQ ID NO: 29, or a complement thereof, or a polypeptide of SEQ ID NO: 30. Use of the limitation "pharmaceutical" in the claim stands for intended use of the composition for therapeutic purposes. In view of the lack of the disclosure of a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect, and also total lack of information or guidance on how to use novel SOC-3/CRAC-2 molecules for treatment of any disease or pathological condition, the instant specification is not found to be enabling for the claimed pharmaceutical composition. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicants' invention as currently claimed.

5. Claims 1, 6-9, 12 and 34 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 6-8 are directed to isolated nucleic acid molecules with deletions, additions and substitutions which code for SOC-3/CRAC-2 polypeptide, nucleic acid molecules that differ from the nucleic acid molecule of SEQ ID NO: 29 due to the degeneracy of the genetic code, various unique fragments of SEQ ID NO: 29 and polypeptides encoded by these nucleic acid molecules, as well fragments of these polypeptides. Claims 9, 12 and 34 are dependent claims.

However, the instant specification fails to describe the entire genus of nucleic acid molecules and polypeptides, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 30. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO: 29 and is designated SOC-3/CRAC-2. The subject matter, which is claimed, is described above. The claims are drawn to isolated nucleic acid molecules with deletions, additions and substitutions which code for SOC-3/CRAC-2 polypeptide, nucleic acid molecules that differ from the nucleic acid molecule of SEQ ID NO: 29 due to the degeneracy of the genetic code, various unique fragments of SEQ ID NO: 29 and polypeptides encoded by these nucleic acid molecules. First, the claims are not limited to a nucleic acid molecule or encoded protein with a specific nucleic or amino acid sequence. The claims only require the nucleic acid or polypeptide to share some degree of structural similarity to the isolated nucleic acid of SEQ ID NO: 29 or polypeptide of SEQ ID NO: 30, respectively. The specification only describes a nucleic acid molecule having the amino acid sequence of SEQ ID NO: 29 and polypeptide of SEQ ID NO: 30, identified as SOC-3/CRAC-2, and fails to teach or describe any other nucleic acid molecule or protein which lacks these nucleic or amino acid sequence structure and has the activities possessed by SOC-3/CRAC-2 polypeptide. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification and because there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the nucleic acid of SEQ ID NO: 29 and protein of SEQ ID NO: 30. The specification does not provide a complete structure of those isolated nucleic acid molecules with deletions, additions and substitutions which code for SOC-3/CRAC-2 polypeptide, nucleic acid molecules that differ from the nucleic acid molecule of SEQ ID NO: 29 due to the degeneracy of the genetic code, various unique fragments of SEQ ID NO: 29 and polypeptides encoded by these nucleic acid molecules. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide a representative number of species for the claimed genus (those isolated nucleic acid molecules with deletions, additions and substitutions which code for SOC-3/CRAC-2 polypeptide, nucleic acid molecules that differ from the nucleic acid molecule of SEQ ID NO: 29 due to the degeneracy of the genetic code, various unique fragments of SEQ ID NO: 29 and polypeptides encoded by these nucleic acid molecules) because the specification teaches only the embodiment of SEQ ID NO: 29 encoding polypeptide of SEQ ID NO: 30. Therefore, the claims are directed to subject matter which was not described in the specification in such a

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. Claims 1, 4, 9, 12 and 34 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 encompasses a nucleic acid molecule, which hybridizes to a nucleic acid molecule of SEQ ID NO: 29 (which makes the claimed nucleic acid complementary to SEQ ID NO: 29) and "which code for a SOC/CRAC polypeptide", emphasis added. Claims 4, 12 and 34 are dependent claims. Claim 9 is drawn to a nucleic acid encoding a polypeptide, while claim 9 depends from claim 6, which encompasses a compliment of a nucleic acid of SEQ ID NO: 29. The prior art clearly does not teach how to produce a polypeptide by using a nucleic acid that is complementary to a nucleic acid encoding that polypeptide. The instant specification fails to provide any guidance or any working examples on how to practice the claimed invention. It would require substantial amount of undue experimentation on part of a skilled artisan in order to discover how to practice Applicant's invention as currently claimed.

7. Claims 9 and 12 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 9 encompasses an isolated nucleic acid encoding a polypeptide. Claim 12 encompasses a polypeptide encoded by a nucleic acid of claim 6. Both claims 9 and 12 depend

from claim 6, which recites fragments of a nucleic acid molecule of SEQ ID NO: 29. Applicant is advised that "a fragment" encompasses fragments as short as one nucleotide, which clearly do not encode any amino acid, peptide or a polypeptide. The prior art clearly does not teach how to produce a polypeptide by using a nucleic acid fragment consisting of one nucleotide. The instant specification fails to provide any guidance or any working examples on how to practice the claimed invention. It would require substantial amount of undue experimentation on part of a skilled artisan in order to discover how to practice Applicant's invention as currently claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 4, 6-9, 12 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is indefinite and ambiguous for recitation of hybridization "under stringent conditions". Without providing a precise set of hybridization conditions, in the claim or the specification, the metes and bounds of the claimed isolated nucleic acid molecule cannot be defined.

10. Claims1 and 12 are vague and indefinite in so far as it employs the term "SOC/CRAC" as a limitation. This term is appears to be novel, and without a reference to a precise amino acid sequence identified by a proper SEQ ID NO: one cannot determine the metes and bounds of "SOC/CRAC". Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "SOC/CRAC", an

artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

11. Claim 1 is further vague and ambiguous with respect to section (b). It appears that in section (b) the claimed subject matter is limited to "deletions, additions and substitutions of (a)" (nucleic acid molecules) rather than "nucleic acid molecules with deletions, additions and substitutions". Clarification is required.

12. Claims 6 and 12 are indefinite and vague for recitation "unique fragment". The metes and bounds of the limitation "unique" cannot be determined from the claims or the instant specification.

13. Claim 6 uses negative limitations, such as "a sequence [...] which is not identical to any sequence", which render the claimed subject matter indefinite. Moreover, Table I appears to recite only one sequence, SEQ ID NO: 9, and not "SEQ. ID NOS". Also, reference to GenBank accession number without providing disclosure of the sequences contained in the deposits makes it impossible to determine if a compound which meets all other limitations would also meet the limitation being "not identical to any sequence [having a sequence of] GenBank accession numbers of Table I".

14. Claim 6 is ambiguous and indefinite for recitation "(3) fragments of [unique fragment of (a)]". Taking into account that a fragment recited in section (a) encompasses a single nucleotide (see reasoning in section 7 of the instant office action), the metes and bounds of "a fragment" recited in section (3) cannot be determined from the claim or the instant specification. Clarification is required.

15. Claim 34 is vague and ambiguous for recitation "expression product". Because claim 1, from which claim 34 depends, encompasses nucleic acid molecules that do not express any products, the metes and bounds of the recitation cannot be properly determined. Clarification is required.

Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.

OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER